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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/743,781 | 03/28/2001 | Daniel Paris | 12062.105014 | 7516 |

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| EXAMINER |
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ANDERSON, JAMES D

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/743,781

Applicant(s)

PARIS ET AL.

Examiner

James D. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 22-30 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' arguments, filed 6/15/2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The examiner assigned to the instant application has changed. The new examiner is James D. Anderson. Contact information is provided at the end of this action.

Status of the Claims

Claims 1, 3 and 22-30 are currently pending and are the subject of this Office Action.

Priority

Upon review, no support is found in priority document 60/092,570 (filed 7/13/1998) for the specific administration of *secretory* phospholipase A2 inhibitors or for the treatment of cerebral amyloid angiopathy or vascular amyloidosis. As such, the earliest effective US filing date for the instant claims has been determined to be 7/13/1999, the filing date of PCT/US99/15947, which discloses the administration of secretory phospholipase A2 inhibitors and the treatment of cerebral amyloid angiopathy or vascular amyloidosis (page 19).

Election/Restrictions

Examiner notes that there have been multiple Elections/Restrictions in the instant case.

In order to clarify the record, the Elections/Restrictions are summarized below.

In response to the Election/Restriction Requirement mailed 10/2/2002, applicants elected, with traverse, Claims 1-3, drawn to a method of modifying vasoactivity by regulating a soluble A β pro-inflammatory pathway in their reply filed 10/30/2002.

Examiner submitted a new Election/Restriction Requirement on 3/4/2003, wherein applicants again elected, with traverse, Claims 1-3, drawn to a method of modifying vasoactivity by regulating a soluble A β pro-inflammatory pathway and the species P38MAP kinase inhibitor as the A β pro-inflammatory pathway regulator in their reply filed 6/6/2003.

The Election/Restriction Requirement was maintained and made final in the Office Action mailed 10/27/2003.

In response to applicant's amendments filed 10/20/2005, examiner required a further election of a specific *secretory* phospholipase A2 inhibitor in the Office Action mailed 1/13/2006.

Applicant's election without traverse of the secretory phospholipase A2 inhibitor oleyloxyethylphosphocholine in the reply filed on 6/15/2006 is acknowledged. The elected species has been found free of the prior art. As such, the Election of Species Requirement is hereby withdrawn and the search has been expanded to include other species of sPLA2 inhibitors.

Claim Objections

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 depends from claim 1, which recites the administration of a “secretory phospholipase A2 inhibitor.” Claim 22, however, recites the limitation wherein the “phospholipase A2 inhibitor” can be AACOCF3. It is noted that applicants state in the specification that AACOCF3 is a cPLA2 inhibitor, not a sPLA2 inhibitor (page 19). As such, claim 22 expands, rather than limits, claim 1.

Claim Rejections - 35 USC § 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 and 23-30 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to methods comprising the administration of a “secretory phospholipase A2 inhibitor.” Thus, the claims are drawn to a sub-genus (*secretory* PLA₂ inhibitors) of compounds that are defined only by biological activity.

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To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of the complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present is that the agent inhibits secretory phospholipase A2. There is no description of structural characteristics are required to retain biological activity. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 111, clearly states, “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed *supra*, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of “secretory phospholipase A2 inhibitor”, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or synthesis. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or synthesizing it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

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Therefore, only the particular compounds recited in dependent claim 22, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes it clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see *Vas-Cath* at page 1115). See also *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement).

Claim Rejections - 35 USC § 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 27, 28 and 30 recite the limitation "phospholipase A2 inhibitor" in Line 1 of each respective claim. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

No claims are allowed. The claims are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



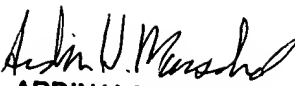
James D. Anderson, Ph.D.
Patent Examiner
AU 1614

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October 4, 2006

 10/8/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER